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Signed Andrew Gerry

Dated 1 December 1997

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Request for grant of a patent

(See the notes on the back of this form. You can also get an explanatory leaflet from the Patent Office to help you fill in this form)

The Patent Office

Cardiff Road
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1. Your reference MPS/6399

2. Patent application number *(The Patent Office will fill in this part)* **9621614.8** 17 OCT 1996

3. Full name, address and postcode of the or of each applicant *(underline all surnames)*

Cultech Limited
York Chambers, York Street, Swansea, SA1 3NJ.

Patents ADP number *(if you know it)* 7659600001

If the applicant is a corporate body, give the country/state of its incorporation United Kingdom

4. Title of the invention

Vitamin Delivery

5. Name of your agent *(if you have one)*

"Address for service" in the United Kingdom to which all correspondence should be sent *(including the postcode)*

Swindell & Pearson

48 Friar Gate,
Derby DE1 1GY

Patents ADP number *(if you know it)* 00001578001

6. If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications and *(if you know it)* the or each application number

Country	Priority application number *(if you know it)*	Date of filing *(day / month / year)*

7. If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application

Number of earlier application	Date of filing *(day / month / year)*

8. Is a statement of inventorship and of right to grant of a patent required in support of this request? *(Answer 'Yes' if:*

a) any applicant named in part 3 is not an inventor, or
b) there is an inventor who is not named as an applicant, or
c) any named applicant is a corporate body.
See note (d))

Yes

9. Enter the number of sheets for any of the following items you are filing with this form. Do not count copies of the same document

Continuation sheets of this form	0
Description	5
Claim(s)	0
Abstract	0
Drawing(s)	1

10. If you are also filing any of the following, state how many against each item.

Priority documents	
Translations of priority documents	
Statement of inventorship and right to grant of a patent *(Patents Form 7/77)*	
Request for preliminary examination and search *(Patents Form 9/77)*	
Request for substantive examination *(Patents Form 10/77)*	
Any other documents *(please specify)*	

11. I/We request the grant of a patent on the basis of this application.

Signature Swindell & Pearson Date 16/10/96

Swindell & Pearson

12. Name and daytime telephone number of person to contact in the United Kingdom: Mr. M.P. Skinner, 01332 367051

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After an application for a patent has been filed, the Comptroller of the Patent Office will consider whether publication or communication of the invention should be prohibited or restricted under Section 22 of the Patents Act 1977. You will be informed if it is necessary to prohibit or restrict your invention in this way. Furthermore, if you live in the United Kingdom, Section 23 of the Patents Act 1977 stops you from applying for a patent abroad without first getting written permission from the Patent Office unless an application has been filed at least 6 weeks beforehand in the United Kingdom for a patent for the same invention and either no direction prohibiting publication or communication has been given, or any such direction has been revoked.

Notes

a) If you need help to fill in this form or you have any questions, please contact the Patent Office on 0645 500505.

b) Write your answers in capital letters using black ink or you may type them.

c) If there is not enough space for all the relevant details on any part of this form, please continue on a separate sheet of paper and write "see continuation sheet" in the relevant part(s). Any continuation sheet should be attached to this form.

d) If you have answered 'Yes' Patents Form 7/77 will need to be filed.

e) Once you have filled in the form you must remember to sign and date it.

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Vitamin Delivery

The present invention relates to vitamin delivery and particularly, but not exclusively, to the preparation of vitamins for delivery to subjects on a voluntary basis without medical prescription.

It is well recognised that various deficiency disorders can arise if vitamin intake is not adequate and for this reason, the health authorities in many countries specify recommended daily allowances (RDAs) of various vitamins for children and adults. Vitamins can be delivered to the subject in a number of ways. The most common form is for a discrete dosage to be ingested in tablet form or by hard or soft gelatine capsules, or by means of powders or liquids. Another common technique of delivering vitamins is by "fortifying" food or beverage products with additional prophylactic components such as vitamins. These food and beverage products may be soft drinks, cereals, dairy products, fruit juices or confectionery.

Capsules, tablets and other discrete dosage forms have the disadvantage that bulking agents (or excipients) are usually required in order to produce a tablet which is sufficiently large for convenient handling and storage. In consequence, the subject taking the capsule or tablet will ingest a considerable amount of bulking agent (which is wholly unnecessary to the prophylactic purpose) along with the desired vitamin content.

For marketing to children in particular, various fruit flavourings, natural colours and fruit powders have been used to produce tablets which are more palatable and therefore more likely to be used with adequate regularity, but considerable volumes of excipient are required.

The present invention seeks to improve vitamin delivery.

The invention provides a method of preparing a vitamin for delivery to a subject, in which at least one vitamin is added to a wet carrier to form a mix which is subsequently freeze-dried, the freeze-dried mix being ingestible.

The term "wet" is used to indicate a form which incorporates more than a negligible amount of water, e.g. a form in which water can be extracted by a freeze-drying process. Preferably the vitamin or vitamins are in solubilised form. Some vitamins are soluble in water; others require treatment to allow emulsification for dispersal in water. Vitamin mixtures are commercially available which contain soluble vitamins and treated insoluble vitamins. The term solubilised is used herein to encompass soluble vitamins, treated insoluble vitamins and mixtures of these.

The wet carrier is preferably a natural material and may be formed from fruit. The wet carrier may comprise fruit juice and/or fruit pulp.

A blend of vitamins may be added as aforesaid. The amount of vitamin added to the carrier may be calculated by reference to the vitamin content or concentration required in the freeze-dried product.

Preferably the mix is freeze-dried in discrete units. The vitamin concentration in the mix is preferably chosen to cause each freeze-dried unit to incorporate a predetermined dose of vitamin. The predetermined dose may be a recommended daily allowance or simple fraction thereof.

The invention also provides a vitamin delivery product comprising an ingestible freeze-dried mix of at least one vitamin and a carrier.

The carrier is preferably a natural material and may be formed from fruit. The carrier may be formed from fruit juice and/or fruit pulp.

Preferably the product comprises a blend of vitamins. The mix is preferably freeze-dried in discrete units, with each unit preferably incorporating a predetermined dose of vitamin, such as a recommended daily allowance.

The present invention will now be described in more detail, by way of example only, and with reference to the accompanying drawings, in which:-

Fig. 1 is a highly schematic diagram illustrating a first stage of a method according to the invention; and

Fig. 2 illustrates a later stage of the method of Fig. 1.

The method to be described is for preparing a vitamin for delivery to a subject, such as a human, and is particularly applicable to vitamin supplements for delivery on a voluntary basis, without medical supervision, such as vitamin delivery products intended to provide a recommended daily allowance of one or more vitamins.

In order to produce the product, a wet carrier is first produced (indicated at 10 in Fig. 1) and introduced into a mixing vessel 12. The wet carrier is preferably a natural material which may be formed from fruit. It is envisaged that fresh or frozen fruit can be formed into a puree or juice (by removal of fruit pulp) to serve as the wet carrier. Typical fruit pulps will have a dry solids content of approximately 10% to 13%, while typical fruit juice will have a dry solids content of approximately 5% to 10%. Concentrates with higher solids contents could be used The wet carrier 10 is introduced into the mixing vessel 12.

A vitamin or mixture of vitamins is then formed (indicated at 14 in Fig. 1) in a solubilised form and added to the wet carrier already in the mixing vessel 12. Naturally the sequence can be reversed, but it is envisaged that the volume of carrier will exceed the volume of vitamin material and thus that mixing will be facilitated by the introduction of vitamin into the carrier, rather than vice versa.

The contents of the vessel 12 are then mixed to a homogeneous mixture, with agitation or other mixing technique. The solubilised form of the vitamin content enhances the homogeneity of the mixture.

The homogeneous mixture so formed is then dispensed from the vessel 12 into individual cavities 16 of a mould tray 18 (Fig. 2). This task of

dispensing is illustrated schematically by means of a pipette 20 but any alternative arrangement appropriate to the nature of the material and volumes to be dispensed could be used.

The contents of the tray 18 are then freeze-dried to substantially remove the water content thereof. Since freeze-drying involves minimal shrinkage of the dry solids content of the mix, the result is a block of dried material in each mould 16 and having the shape and size of the packet of liquid originally introduced into the mould 16. These dried units can then be removed from the moulds and packaged in an appropriate manner, such as in blister packs for retail sale as a vitamin supplement.

The vitamin delivery product so produced will contain only the dried fruit and vitamin, without excipient. Its taste will be virtually wholly determined by the original fruit content of the carrier 10. This is expected to provide a palatability and mouth feel which are greatly improved over known vitamin supplements and similar products, so that the product described is expected to be well received in the children's market.

It is preferred that each dried unit contains a recommended daily allowance of the vitamin or vitamin blend, or a simple fraction thereof (such as a half, quarter etc.).

The concentration of vitamins required in the mix formed in the vessel 12 can be calculated as follows. First, the vitamin dose to be delivered by each unit is chosen. This might, for instance, be 100mg. Secondly, the volume of the final unit is chosen (perhaps 1ml), largely for practical reasons of handling and user preference. The mix in the vessel 12 is thus required to have a vitamin concentration of one dose per final unit volume. Other factors may influence final choices. For instance, some vitamins have stronger or more unpleasant tastes than others, requiring a higher ratio of fruit content to vitamin content to disguise the vitamin taste. The final unit volume might therefore be increased to assist in this way. The dry solids content of the fruit

component also affects the final product, in that a material with a higher dry solids content is more likely to adequately mask a vitamin taste, than would a material with a lower dry solids content. These factors may affect the choice of fruit material (e.g. the fruit type) or the form (juice, fruit pulp, concentrate etc.). The mouth feel and taste are affected by these choices. A final product can be produced which consists of a honeycomb structure of dried fruit solid, through which the vitamin dose is evenly distributed, and which has an acceptable taste and texture in the mouth.

It is expected that the technique can be applied to a wide variety of natural materials, particularly a wide variety of fruit juices and pulps, and to many different vitamins and vitamin blends, so that a wide range of vitamin delivery products can be produced for many different purposes.

Whilst endeavouring in the foregoing specification to draw attention to those features of the invention believed to be of particular importance it should be understood that the Applicant claims protection in respect of any patentable feature or combination of features hereinbefore referred to and/or shown in the drawings whether or not particular emphasis has been placed thereon.

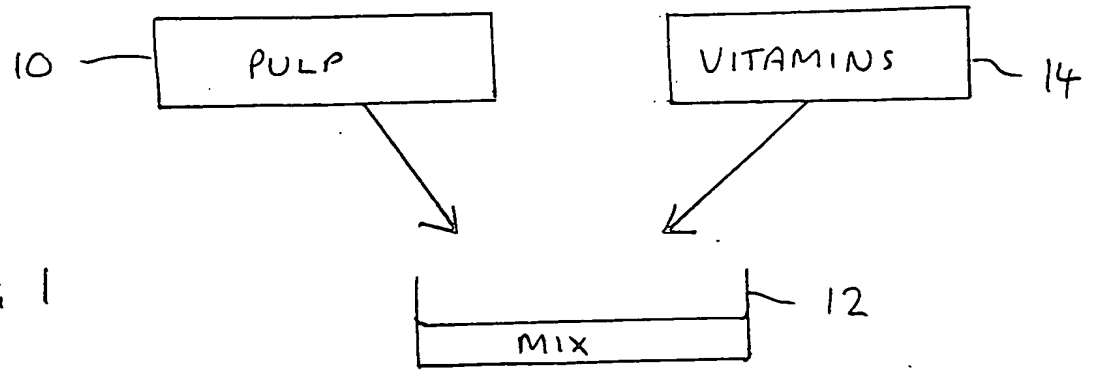

FIG 1

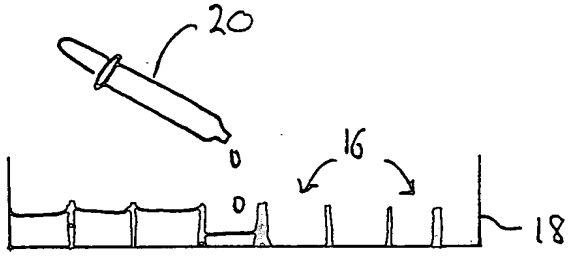

FIG 2

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17 NOV 1997